

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS OPPOSITION TO INDIVIDUAL MEMORANDUM OF BAYER CORPORATION IN SUPPORT OF MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Bayer Corporation's ("Bayer") memorandum (hereinafter "Bayer MTD") seeks the dismissal of claims relating to Kogenate, Gamimune, Cipro and Adalat CC, and other Bayer products. With regard to the specifically identified drugs, Bayer contends that all claims are barred either by a 2001 or a 2003 settlement with New York. With regard to all "other Bayer products", Bayer argues that such claims are not pled with sufficient particularity to satisfy Fed. R. Civ. P. 8(a) and 9(b) because plaintiffs rely only on the settlements to support allegations of Bayer misconduct.

Plaintiffs allege fraud in AWP and Best Price reporting.¹ Claims arising from Bayer's misconduct not specifically covered by the settlements should be sustained. Indeed, this Court has already ruled for plaintiffs on this point.² As for claims regarding other Bayer products, they meet the particularity requirements of Fed. R. Civ. P. 8(a) and 9(b) as well as the Court's prior rulings, including *County of Suffolk v. Abbott Labs., et al.*³

DISCUSSION

A. The 2001 Settlement Only Releases Claims from January 1993 through August 1999.

The NY Counties seek to recover Medicaid overpayments for Bayer's products Kogenate, Gamimune, Cipro and Adalat CC,⁴ among other drugs, "from 1992 to the present ..." CC ¶1; NSAC ¶1 (emphasis added).

¹The specific allegations as to Bayer's fraudulent pricing appear at Corrected Consolidated Complaint, filed on June 22, 2005 ("Consolidated Complaint" or "CC") at ¶¶307-327; Nassau Second Amended Complaint, filed on January 6, 2006 ("Nassau SAC" or "NSAC") at ¶¶288-296 and exhibit A to plaintiffs' opposition to the consolidated motion to dismiss.

²See *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2004 WL 2387125, at *3 (D. Mass., Oct. 26, 2004) ("*Suffolk II*")

³See *In re Pharm. Indus. Average Wholesale Price Litig.* 339 F.Supp.2d 165, 173 ("*Suffolk I*"); *Suffolk II* 2004 WL 2387125, at *3; *In re Pharm. Indus. Average Wholesale Price Litig.* Memorandum and Order at 1-2 (D. Mass. April 8, 2005) ("*Suffolk III*"). Plaintiffs address all other causes against Bayer in their brief opposing defendants' consolidated motion to dismiss, filed contemporaneously herewith.

⁴See Corrected Consolidated Complaint, filed on June 22, 2005 ("Consolidated Complaint" or "CC") at ¶¶ 307, 326-27; CC Exh. A; Nassau Second Amended Complaint, filed on January 6, 2006 ("Nassau SAC" or "NSAC") at ¶¶ 288, 304-306; NSAC Exh. B.

Bayer contends that the 2001 Settlement releases all of plaintiffs' claims for Kogenate and Gamimune. Bayer MTD at 3. This mischaracterizes the scope of the 2001 Settlement's release.⁵ As Bayer admits elsewhere in its brief, the scope of the 2001 Settlement resolved allegations "that Bayer improperly inflated the AWP's of the drugs ... **from January 1993 through August 1999.**" Bayer MTD at 2 (emphasis added). Plaintiffs agree that the claims regarding Kogenate and Gamimune within the settlement period were resolved by the defined scope of the 2001 Settlement. Plaintiffs' claims relating to Kogenate and Gamimune for conduct occurring beyond the settlement period were not released.

B. The 2003 Settlement Only Resolves Plaintiffs' Best Price Claims Relating to Cipro and Adalat for the Scope of the Settlement.

Bayer posits that the 2003 Settlement released all of plaintiffs' rebate claims for Cipro and Adalat. The 2003 Settlement, however, covers only the Third Quarter of 1995 to the Third Quarter of 2000 for Cipro and the Second Quarter of 1997 to the Third Quarter of 2000 for Adalat. Plaintiffs agree that the 2003 Settlement releases their Best Price (not AWP) claims for Cipro and Adalat for these time periods. The Court already ruled as such for Cipro.⁶ Plaintiffs' Cipro and Adalat claims beyond the period of the 2003 Settlement were not released. *See id.*

C. Plaintiffs' Best Price Claims Against Bayer Should Be Sustained.

Bayer contends that plaintiffs only allege particular facts for Cipro and Adalat in support of their Best Price claims and as such all other Best Price Claims should be dismissed under Fed. R. Civ. P. 8(a) and 9(b). This is false.

⁵There is absolutely no language tying the release of claims to the effective date of the agreement, nor is there any language expanding the scope of the release of claims beyond the January 1993 to August 1999 time period. *See* Bayer MTD, Exhibit 1 (2001 Settlement).

⁶*See In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2004 WL 2387125 at *3 (D. Mass., Oct. 26, 2004) ("*Suffolk II*") (AWP claims against Bayer for Cipro not barred by the settlement agreements. Suffolk's Best Price claims for Cipro from Third Quarter 1995 to Third Quarter 2000 are barred). The applicability and scope of the 2003 Settlement to Adalat and the 2001 Settlement to Kogenate and Gamimune were not addressed.

In order to maintain Best Price claims, plaintiffs must “set forth minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices.” *Suffolk II* 2004 WL 2387125, at *3.

Plaintiffs have done both. First, plaintiffs allege the name of every Bayer drug for which they assert Best Price claims. *See* CC Exh. A & B; NSAC Exh. A & B. Second, plaintiffs allege a company-wide scheme and strategy whereby Bayer’s sales force had the discretion to utilize off-invoice pricing to lower prices and maximize sales. Plaintiffs allege that off-invoice pricing allows manufacturers to lower the net cost to the purchaser while concealing the actual cost beneath the fiction of a higher invoice price. *See* CC ¶¶ 153, 307-327; NSAC ¶¶ 122, 293. The Court already has determined that such allegations suffice to state Best Price claims against Bayer. *Suffolk II* 2004 WL 2387125, at *3.

Plaintiffs also allege that: (1) Bayer’s sales force utilized off-invoice pricing to achieve sales goals and to improperly avoid Medicaid risks; (2) Bayer did so with at least three of its customers; (3) Bayer utilized, and did not account for, off-invoice price reductions in the form of marketing grants, special educational grants and/or data gathering fees to make up for the falsely inflated invoices and to mask the true lower cost of the drugs on the invoice; and (4) Bayer told its sales force that the best way to quickly lower prices, maximize sales and avoid Medicaid Best Price implications was to use off-invoice pricing. These allegations show a company-wide scheme implicating all Bayer products. *See* CC at ¶¶ 307-327; NSAC at ¶¶ 288-296.

Moreover, the 2001 and 2003 settlements make plain that Bayer’s misconduct in respect of rebate activities is not speculative. The 2001 Settlement shows that Bayer utilized off-invoice pricing to misstate its Best Prices for five drugs: Koate-HP, Kogenate, Konyne-80, Gamimune and

Thrombate. The 2001 Settlement provided evidence that Bayer knowingly and intentionally misled Medicaid reimbursement programs by (i) inflating AWP and hiding true WAC, (ii) falsely reporting pricing by providing invoices to health companies that did not reflect true net cost, and (iii) underpaying its Medicaid rebates by calculating its Best Price without factoring in the value of discounts, rebates, short-dated goods discounts, unrestricted educational grants, free goods, chargebacks and other price reductions. *See* 2001 Settlement Part II, ¶C. The 2003 Settlement provides evidence that Bayer fraudulently misled Medicaid reimbursement programs through its practice of “private labeling” Cipro and Adalat to hide the true pricing of the drugs. *See* 2003 Settlement Part II Preamble ¶F.

D. Plaintiffs’ AWP Claims Against Bayer Should Be Sustained

Bayer says that plaintiffs fail to plead their AWP claims with sufficient particularity because plaintiffs: (i) rely only on the 2001 and 2003 settlement agreements; and, (ii) showed only the “Fraudulent AWP”, “Market Prices” and “Spreads”.⁷ *See* Bayer MTD at 4. The argument ignores entirely the Court’s prior rulings regarding pleading AWP claims with particularity and that the Court sustained Suffolk’s AWP claims against Bayer. *See Suffolk II*, 2004 WL 2387125, at *2; *Suffolk III* at 3.⁸

In order to maintain AWP Claims, plaintiffs must set forth factual allegations regarding spread, internal documents or government investigations from which an inference of fraud can

⁷Bayer contends that any claims by Nassau County with respect to drugs listed in NSAC Exhibit A, but not in NSAC Exhibit B must be dismissed for a lack of standing. The Nassau SAC squarely addresses the role of Exhibits A and B. Exhibit A contains information on reported AWP and available market prices for Bayer drugs. Exhibit B contains information on drugs purchased by Nassau County in 2003. “Exhibit B does not include information for every drug for which Nassau County claims to have overpaid. Defendants control the information Nassau County would need to create a comprehensive list.” NSAC at ¶183 n. 7. Since all of the AWP and price information for Bayer drugs are from December 2000, and the data contained in Exhibit B are reflective of information from 2003, the two sets of data do not, and furthermore are not, required to align.

⁸The Court dismissed plaintiffs’ AWP claims against the “Suffolk 13 + 6”. *See Suffolk III* at 3. Bayer was not in this group.

reasonably be made. *See Suffolk II*, 2004 WL 2387125, at *2; *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 209 (D. Mass. 2004)(“*Pharm. III*”). In alleging a spread, a calculated actual average price for a drug will not suffice. *See Suffolk III* at 2.

Plaintiffs have done this by (1) detailing the fraudulent AWP and related spread from actual prices paid -- not an average price -- for Bayer products; (2) discussing the misconduct from the two settlement agreements; (3) providing details of recent government investigations by the Dept. of Justice, the Commonwealth of Massachusetts and the Office of Inspector General for Health and Human Services for Bayer AWP and Best Price violations; and (4) detailing the company-wide off-invoicing scheme to further inflate the spread between AWP and invoiced purchases. *See* CC ¶¶ 307-327, Exh. A & B; NSAC ¶¶288-306, Exh. A & B.

The foregoing is certainly sufficient to draw a reasonable and decidedly sound inference of a company-wide AWP Fraud in compliance with the requirements of Fed. R. Civ. P. 9(b) and 8(a). *See U.S. ex rel Franklin v. Parke Davis*, 147 F.Supp.2d 39, 49 (D.Mass 2001)(Saris, J.)(“[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.”)

Second, as indicated in Point C *supra*, the 2001 and 2003 Settlements are entirely relevant and probative to plaintiffs’ fraud based claims in this case. In the 2003 settlement Bayer actually entered a criminal plea. Such settlements resulting from a government investigation are entirely relevant here. *See Suffolk II*, 2004 WL2387125, at *2; *see also Pharm III*, 307 F. Supp.2d at 209.

E. Other Claims

Finally, Bayer does not dispute – nor could it – that plaintiffs’ allegations state AWP and Best Price unjust enrichment claims, and claims for 18 N.Y.C.R.R. §515.2(b)(4) & (5) and N.Y. Soc. Serv. Law §367-a(7)(d). The Court ruled that Fed. R. Civ. P. 9(b) does not apply to such

claims. *Suffolk II*, 2004 WL2387125, at *2.

CONCLUSION

For the reasons set forth herein, only claims against Bayer covered by the 2001 Settlement Agreement and 2003 Settlement Agreement for the time period discussed herein should be dismissed.

Dated: April 17, 2006

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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